DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 4, 2014

Nestle HealthCare Nutrition, Inc.
% M.W. (Andy) Anderson, Ph.D., RAC
Senior Principal Advisor, Regulatory Affairs
and Quality Systems
Regulatory & Clinical Research Institute, Inc. (RCRI)
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416

Re: K140947
Trade/Device Name: Compat® Enteral Delivery Pump Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: August 15, 2014
Received: August 18, 2014

Dear M.W. (Andy) Anderson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indication for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
N/A K140947

Device Name

Compat® Enteral Delivery Pump Set

Indications for Use *(Describe)*

The Compat® Enteral Delivery Pump Sets are intended to deliver liquid nutrition formulas or hydration to an enteral access device (a feeding tube).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Summary (21 CFR § 807.92)

Submitter:	Nestlé HealthCare Nutrition, Inc.
Contact:	Thomas A. Dold
Date Prepared:	29 August 2014
Establishment Registration Number:	2110851
Trade Name:	Compat® Enteral Delivery Pump Sets
Common Name:	Tubes, gastrointestinal and accessories
Device Classification:	Gastrointestinal Tubes with Enteral Specific Connectors
Class:	II
Product Code:	PIF
Regulation:	21 CFR 876.5980
Classification Panel:	Gastroenterology/Urology
Predicate Device(s):	COMPAT DualFlo® Enteral Delivery Pump Set with SpikeRight Piercing Spike and 1000 mL Water Bag K080340
Device Description:	Five configurations of enteral delivery sets: Standard Bag, Standard SpikeRight® PLUS, DualFlo Bag/SpikeRight PLUS, DualFlo Bag/Bag and Gravity Set for administering liquid nutrition or hydration to an enteral access device (feeding tube).
Intended Use:	The Compat Enteral Delivery Pump Sets are intended to deliver liquid nutrition formulas or hydration to an enteral access device (a feeding tube)
Technological Characteristics:	Single-use enteral delivery sets consist of PVC tubing, formula/water bag, drip chamber, ABS SpikeRight PLUS and ENFit connectors with roller or slide clamps.
Performance Testing (Bench):	The following performance testing was conducted on the Compat Enteral Delivery Administration Sets: • *Risk Assessment of the Administration Sets including Failure Modes and Effects Criticality Analysis (FMECA)*

- *ENFit component verification testing*
- *ENFit bond strength testing*
- *PGLOCK Administration Validation Testing*
- *ASTM D638-10: Standard Test Method for Tensile Properties of Plastics*
- *Performance testing with and without reference connectors:*
  - *Falling drop positive pressure liquid leakage*
  - *Stress cracking*
  - *Resistance to separation from axial load*
  - *Resistance to separation from unscrewing*
  - *Resistance to overriding*
  - *Disconnection by unscrewing*
  - *Falling drop positive pressure liquid leakage after 20 cycles*
- *Enteral Connector Misconnection Assessment Study*
- *Failure Modes and Effects Analysis (FMEA)*
- *Risk Analysis*
- *Human Factors Testing*
- *Biocompatibility Testing (ISO 10993)*
  - *Part 5: Tests for* Invitro *Cytotoxicity*
  - *Part 10: Tests for Irritation and Delayed-Type Hypersensitivity – Intracutaneous Study (rabbits)*
  - *Part 10: Tests for Irritation and Delayed-Type Hypersensitivity – Sensitization Study (guinea pig)*
- Flow Rate Testing to assure ENFit flow rate equals or exceeds step connector flow rate

Performance Testing (Animal): None provided

Performance Testing (Clinical): None provided

Substantial Equivalence Rationale: The Compat Enteral Delivery Administration Sets are substantially equivalent to the approved Nestlé Healthcare Nutrition administration sets except for the replacement of the distal AAMI ID54 (“Christmas tree” or “step”) connector with the ENFit connector tested in accordance with ISO 80369-1.